UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS

KATLYN K. REIN, Individually and on Behalf of All Others Similarly Situated,

Plaintiff,

v.

CASSAVA SCIENCES, INC., REMI BARBIER, ERIC J. SCHOEN, JAMES W. KUPIEC, NADAV FRIEDMANN, and MICHAEL MARSMAN,

Defendants.

Case No. 1:21-cv-856

CLASS ACTION COMPLAINT FOR VIOLATIONS OF THE FEDERAL SECURITIES LAWS

JURY TRIAL DEMANDED

Plaintiff Katlyn K. Rein ("Plaintiff"), individually and on behalf of all others similarly situated, by and through Plaintiff's attorneys, alleges the following upon information and belief, except as to those allegations concerning Plaintiff, which are alleged upon personal knowledge. Plaintiff's information and belief is based upon, among other things, the investigation by Plaintiff's counsel, which includes without limitation: (a) review and analysis of regulatory filings made by Cassava Sciences, Inc. ("Cassava" or the "Company") with the United States ("U.S.") Securities and Exchange Commission ("SEC"); (b) review and analysis of press releases and media reports issued by and disseminated by Cassava; and (c) review of other publicly available information concerning Cassava.

NATURE OF THE ACTION

1. This is a class action on behalf of persons and entities that purchased or otherwise acquired Cassava securities between September 14, 2020 and August 27, 2021, inclusive (the "Class Period"). Plaintiff pursues claims against the Defendants under the Securities Exchange Act of 1934 (the "Exchange Act").

2. Cassava is an Austin-based clinical stage biotechnology company engaged in the development of drugs for neurodegenerative diseases. Its lead therapeutic product candidate is called simufilam (formerly PTI-125) developed as a treatment for Alzheimer's disease ("AD"), and its lead investigational diagnostic product candidate was SavaDx, a blood-based biomarker/diagnostic to detect AD. Simufilam purportedly targets an altered form of a protein called filamin A ("FLNA") in the Alzheimer's brain and reverts it to its native, healthy conformation, thereby countering the downstream toxic effects of altered FLNA. The Company's financial viability is largely dependent upon the clinical success of simufilam as the Company currently has no sources of revenues.

3. On February 2, 2021, Cassava announced results from its interim analysis of an open-label study of simufilam, which purportedly demonstrated that patients' cognition and behavior scores both improved following six months of simufilam treatment, with no safety issues. According to the Company, "[i]n a clinical study funded by the National Institutes of Health and conducted by Cassava Sciences, six months of simufilam treatment improved cognition scores by 1.6 points on ADAS-Cog11, a 10% mean improvement from baseline to month 6," and "[i]n these same patients, simufilam also improved dementiarelated behavior, such as anxiety, delusions and agitation, by 1.3 points on the Neuropsychiatric Inventory, a 29% mean improvement from baseline to month 6."

4. As the market digested this news, the market price of Cassava common stock spiraled up, nearly quadrupling from its close of $22.99 per share on February 1, 2021 to trade as high as $90 per share in intraday trading by February 3, 2021. The stock spiked on extremely high trading volume of more than 76 million shares trading on February 2, 2021 alone, more than 19 times the average daily volume over the preceding ten trading days. Cassava immediately cashed in on the stock price inflation, issuing and selling more than four million shares of its common stock at $49 per share on February 12, 2021 through an underwritten follow-on public stock offering and reaping more than $200 million in gross proceeds (the "Offering").

5. Throughout the Class Period, Defendants made materially false and/or misleading statements, as well as failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors that: (1) the quality and integrity of the scientific data supporting Cassava's claims for simufilam's efficacy had been overstated; (2) data underlying the foundational research for Cassava's product candidates had been manipulated; (3) experiments using post-mortem human brain tissue frozen

for nearly 10 years was contrary to a basic understanding of neurobiology; (4) biomarker analysis for patients treated with simufilam had been manipulated to conclude that simufilam was effective; (5) Quanterix Corp. ("Quanterix"), an independent company, had not interpreted the test results or prepared the data charts for the biomarker analysis for patients treated with simufilam; (6) as a result of the foregoing, there was a reasonable likelihood that Cassava would face regulatory scrutiny in connection with the development of simufilam; and (7) as a result of all the foregoing, Defendants' positive statements during the Class Period about the Company's business metrics and financial prospects and the likelihood of U.S. Food and Drug Administration ("FDA") approval were false and misleading and/or lacked a reasonable basis.

6. On July 29, 2021, Cassava issued a press release entitled "Cassava Sciences Announces Positive Cognition Data With Simufilam in Alzheimer's Disease." Although the press release touted supposedly positive cognition data, analysts and industry observers noted that the data had not demonstrated that simufilam was more effective at improving cognition than Biogen Inc.'s ("Biogen") drug Aduhelm.

7. On this news, Cassava's share price fell $65.77, or 48.61%, over two trading days, to close at $69.53 per share on July 30, 2021.

8. On August 24, 2021, after the market closed, reports emerged about a citizen petition submitted to the FDA concerning the accuracy and integrity of clinical data for simufilam. The petition requested that the FDA halt Cassava's clinical trials pending a thorough audit of the publications and data relied upon by the Company. Among other things, the petition stated that the "[d]etailed analysis of the western blots [relied on by Cassava to support the connection between simufilam and Alzheimer's] shows a series of anomalies that are suggestive of systematic data manipulation and misrepresentation." It also stated that the methodology for studies "about

Simufilam's effects in experiments conducted on postmortem human brain tissue . . . defies logic, and the data presented again have hallmarks of manipulation." The petition further stated that, after initial analyses of Phase 2b trials found that Simufilam was ineffective in improving the primary biomarkers endpoint, "Cassava had these samples analyzed again and this time reported that Simufilam rapidly and robustly improved a wide array of biomarkers" and the reanalysis "shows signs of data anomalies or manipulation."

9. On August 25, 2021, before the market opened, Cassava issued a response to the petition, claiming that the allegations regarding scientific integrity are false and misleading. Among other things, the Company claimed that the clinical data, which the citizen petition stated had been reanalyzed to show simufilam was effective, had been generated by Quanterix, an independent company, suggesting that the reanalysis was valid.

10. On this news, the Company's share price fell $36.97, or 31.38%, to close at $80.86 per share on August 25, 2021, on unusually heavy trading volume.

11. On August 27, 2021, before the market opened, Quanterix issued a statement denying the Company's claims, stating that it "did not interpret the test results or prepare the data" touted by Cassava.

12. The same day, Cassava responded to Quanterix's statement, stating that "Quanterix'[s] sole responsibility with regard to this clinical study was to perform sample testing, specifically, to measure levels of p-tau in plasma samples collected from study subjects."

13. On this news, the Company's share price fell $12.51, or 17.66%, to close at $58.34 per share on August 27, 2021, on unusually heavy trading volume.

14. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

JURISDICTION AND VENUE

15. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

16. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. § 1331 and Section 27 of the Exchange Act (15 U.S.C. § 78aa).

17. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(b) and Section 27 of the Exchange Act (15 U.S.C. § 78aa(c)). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Many of the acts charged herein, including the dissemination of materially false and/or misleading information, occurred in substantial part in this Judicial District. In addition, the Company's principal executive offices are located in this District.

18. In connection with the acts, transactions, and conduct alleged herein, Defendants directly and indirectly used the means and instrumentalities of interstate commerce, including the U.S. mail, interstate telephone communications, and the facilities of a national securities exchange.

PARTIES

19. Plaintiff, as set forth in the accompanying certification, incorporated by reference herein, purchased Cassava securities during the Class Period, and suffered damages as a result of the federal securities law violations and false and/or misleading statements and/or material omissions alleged herein.

20. Defendant Cassava is incorporated under the laws of Delaware with its principal executive offices located in Austin, Texas. Cassava's common stock trades on the NASDAQ under the symbol "SAVA."

21. Defendant Remi Barbier ("Barbier") founded Cassava and served as the Chief Executive Officer ("CEO"), President, and Chairman of the Board of Directors of Cassava at all relevant times.

22. Defendant Eric J. Schoen ("Schoen") served as the Chief Financial Officer of Cassava at all relevant times.

23. Defendant James W. Kupiec ("Kupiec") served as the Chief Clinical Development Officer of Cassava at all relevant times.

24. Defendant Nadav Friedmann ("Friedmann") served as the Chief Medical Officer of Cassava and a member of its Board of Directors at all relevant times.

25. Defendant Michael Marsman ("Marsman") served as the Senior Vice President of Regulatory Affairs at Cassava at all relevant times.

26. Defendants Barbier, Schoen, Kupiec, Friedmann, and Marsman (collectively the "Individual Defendants"), because of their positions with the Company, possessed the power and authority to control the contents of the Company's reports to the SEC, press releases and presentations to securities analysts, money and portfolio managers and institutional investors, *i.e.*, the market. The Individual Defendants were provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being

concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein.

SUBSTANTIVE ALLEGATIONS

Background

27. The World Health Organization reports more than 50 million people worldwide suffer from the deterioration of memory, thinking, and behavior that is associated with dementia, and Alzheimer's is the most common type of dementia, representing 60% to 70% of dementia patients.

28. Cassava's product portfolio includes a small molecule drug for the treatment of AD, called simufilam, and an investigational blood-based diagnostic to detect and monitor the progression of AD, called SavaDx. Simufilam purportedly targets an altered form of FLNA in the Alzheimer's brain and reverts it to its native, healthy conformation, thereby countering the downstream toxic effects of altered FLNA. The Company's financial viability is largely dependent upon the clinical success of simufilam as the Company currently has no sources of revenues.

29. Another, much larger pharmaceutical company called Biogen, recently obtained FDA approval for its own Alzheimer's therapy, Aduhelm. Cassava's simufilam, a twice-daily oral tablet, would likely be much less expensive than Aduhelm, which is given via a monthly intravenous injection and is expected to cost $56,000 a year per patient. A lower cost and greater ease of use was expected to provide significant competitive advantages for Cassava's lead drug. However, these competitive advantages and the market potential for simufilam depended on the Company receiving FDA approval for the treatment.

Materially False and Misleading Statements Issued During the Class Period

30. The Class Period begins on September 14, 2020, when Cassava announced the final results from its Phase 2b clinical study of simufilam in a press release that stated, in relevant part[1]:

> Cassava Sciences, Inc. (Nasdaq: SAVA) today announced final results of a Phase 2b study with its lead drug candidate, simufilam, in Alzheimer's disease. In a clinical study funded by the National Institutes of Health (NIH), ***simufilam significantly improved an entire panel of validated biomarkers of disease in patients with Alzheimer's disease.*** The ability to improve multiple biomarkers from distinct biological pathways with one drug has never been shown before in patients with Alzheimer's disease. Study results are expected to be published in a peer-reviewed publication. Simufilam is the first of a new class of drug compounds that bind to a protein called Filamin A.
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> "Filamin-binding molecules are new to Alzheimer's research and may represent an important advance if these data can be replicated in larger studies," said Jeffrey Cummings, M.D., Sc.D., Founding Director of the Cleveland Clinic Lou Ruvo Center for Brain Health, and Chambers Professor of Brain Science at the University of Nevada, Las Vegas. "I am pleased to see early evidence of disease-modifying effects in patients with this investigational drug. The data appear to represent a step forward toward urgently needed treatments for Alzheimer's disease."
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> In addition, Alzheimer's patients treated with simufilam showed directional improvements in tests of remembering new information, versus patients on placebo. Improvements in cognition correlated most strongly with decreases in P-tau181, a biomarker that, when elevated, leads to tangles in the brain. Simufilam decreased brain levels of Ptau-181 by 8-11%, versus placebo.
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> ***In this study, Alzheimer's patients treated with 50 mg or 100 mg of simufilam twice-daily for 28 days showed statistically significant ($p<0.05$) improvements in biomarkers of disease pathology, neurodegeneration and neuroinflammation, versus Alzheimer's patients who took placebo. In addition, Alzheimer's patients treated with simufilam showed directional improvements in validated tests of episodic memory and spatial working memory, versus patients on placebo (Effect Sizes 46-17%). Cognitive improvements correlated most strongly ($R2=0.5$) with decreases in P-tau181. The study achieved a 98% response rate, defined as the proportion of study participants taking simufilam who showed improvements in biomarkers.***
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> "The clinical data suggest simufilam may be slowing disease progression in Alzheimer's patients," said Nadav Friedmann, PhD/MD, Chief Medical Officer,

[1] Unless otherwise stated, all emphasis herein is added.

> Cassava Sciences. "This exciting possibility will need to be evaluated in future collaborations with patients, physicians, advisors and others."
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> "Other than a few drugs to help ease the decline, there's really nothing out there to treat people with Alzheimer's," said Remi Barbier, Chairman, President & CEO, Cassava Sciences. "The improvement on multiple biomarkers in this clinical study is a first and offers hope that simufilam has potential to become a transformative treatment for people with Alzheimer's disease."

31. On February 2, 2021, Cassava announced that Simufilam improves cognition and behavior in AD according to the interim analysis from an open-label study. Specifically, the Company stated, in relevant part:

> Cassava Sciences, Inc. (Nasdaq: SAVA) today announced results of an interim analysis from an open-label study of simufilam, its lead drug candidate for the treatment of Alzheimer's disease. Patients' cognition and behavior scores both improved following six months of simufilam treatment, with no safety issues.
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> In a clinical study funded by the National Institutes of Health and conducted by Cassava Sciences, six months of simufilam treatment improved cognition scores by 1.6 points on ADAS-Cog11, a 10% mean improvement from baseline to month 6. In these same patients, simufilam also improved dementia-related behavior, such as anxiety, delusions and agitation, by 1.3 points on the Neuropsychiatric Inventory, a 29% mean improvement from baseline to month 6.
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> Alzheimer's is a progressive disease. Over time, a patient's cognition will always worsen. "Experience based on longitudinal studies of ambulatory patients with mild to moderate Alzheimer's disease suggest that scores on ADAS-cog decline by 6 - 12 points per year", according to FDA's Prescription Information sheet for ARICEPT® (donepezil), a drug approved for the treatment of dementia of the Alzheimer's type1.
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> "We could not be more pleased with these interim results," said Remi Barbier, President & CEO. "We would have been satisfied to show simufilam stabilizes cognition in patients over 6 months. ***An improvement in cognition and behavior tells us this drug candidate has potential to provide lasting treatment effects for people living with Alzheimer's disease.*** It's an exciting development."
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> The safety profile of simufilam in the interim analysis was consistent with prior human studies. There were no drug-related serious adverse events. Adverse events were mild and transient.
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> "***Today's data once again suggests simufilam could be a transformative, novel therapeutic***," added Nadav Friedmann, PhD, MD, Chief Medical Officer. "It

> appears the drug's unique mechanism of action has potential to provide a treatment benefit following 6 months of dosing."

32. As the market digested this news, the market price of Cassava common stock spiraled up, nearly quadrupling from its close of $22.99 per share on February 1, 2021 to trade as high as $90 per share in intraday trading by February 3, 2021. The stock spiked on extremely high trading volume of more than 76 million shares trading on February 2, 2021 alone, more than 19 times the average daily volume over the preceding ten trading days.

33. On February 8, 2021, Cassava issued a press release entitled "Cassava Sciences Announces Significant Program Progress and Expected Key Milestones in 2021 for Its Clinical Program in Alzheimer's Disease." That release stated, in relevant part:

> "We started 2021 with tremendous momentum, led by ***results of a 6-month interim analysis*** from an open-label study of simufilam, our drug candidate for Alzheimer's disease," said Remi Barbier, President & CEO. "I believe the rest of the year may be equally exciting."
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> Cassava Sciences' strategic focus for 2021 is to advance simufilam in a Phase 3 clinical program in Alzheimer's disease, to expand drug manufacturing capabilities in support of the clinical program, and to continue to lead the Company to deliver the full potential of its product portfolio.
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> **Cassava Sciences' 2021 Scientific and Clinical Outlook**
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> Expected progress and key milestones in 2021 across Cassava Sciences' product portfolio are summarized below.
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> - Based on recent ***positive clinical results*** and inbound demand from clinical sites, patients, and their caregivers, Cassava Sciences plans to expand the size of the ongoing open-label study of simufilam. The target enrollment will be increased by up to 50 additional patients with mild-to-moderate Alzheimer's disease, for a total target enrollment of up to 150 patients.
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> - Cassava Sciences has enrolled approximately 80 patients in the open-label study to date. To accommodate increased enrollment, the Company plans to open new clinical sites across the U.S. and Canada.

- Cassava Sciences expects to announce results of a second interim analysis of the ongoing open-label study when approximately 50 patients complete 12 months of drug treatment. This second interim analysis is expected to include clinical data around long-term safety, cognition and Alzheimer's-related behavior.

- Cassava Sciences plans to initiate a 6-month, double-blind, randomized, placebo-controlled study in patients with Alzheimer's disease who complete at least one year of open-label treatment with simufilam. This is a Cognition Maintenance Study (CMS), in which patients who complete one year of open-label treatment will subsequently be randomized (1:1) to simufilam or placebo for six months. The CMS is designed to compare simufilam's effects on cognition and behavior in patients who continue with drug treatment versus those who discontinue drug treatment. For ethical and other reasons, patients who successfully complete the six-month CMS will have the option to receive open-label simufilam.

- Cassava Sciences' clinical and regulatory strategy for simufilam is progressing as planned. In January 2021, the Company concluded a successful End-of-phase 2 (EOP2) meeting with the U.S Food and Drug Administration (FDA). The purpose of the EOP2 was to gain general agreement around a Phase 3 program to treat Alzheimer's disease dementia.

- As a result of the EOP2 meeting, Cassava Sciences believes its clinical program for simufilam is green-lighted to commence a large, Phase 3 clinical program in patients with Alzheimer's disease, pending official FDA meeting minutes of the EOP2 meeting.

- Cassava Sciences plans to initiate a Phase 3 program of simufilam in Alzheimer's disease in the second half of 2021.

- Cassava Sciences' Phase 3 program for simufilam consists of two large, double-blind, randomized, placebo-controlled studies of simufilam in patients with mild-to-moderate Alzheimer's disease dementia. The Company expects to announce details of its Phase 3 program in Q1 2021, pending official FDA meeting minutes of the EOP2 meeting.

- Cassava Sciences' first Phase 3 study will evaluate disease-modifying effects in Alzheimer's disease patients over 18 months. The goal of this study is to show a slower rate of decline in cognition and daily function in patients treated with simufilam, compared to patients treated with placebo.

- Cassava Sciences' second Phase 3 study will evaluate symptomatic improvement in Alzheimer's disease patients over 6 months. The goal of this study is to show improvement in cognition and daily function in patients treated with simufilam, compared to patients treated with placebo.

- Cassava Sciences believes its manufacturing strategy is on-track to ensure sufficient drug supply for a Phase 3 program, including both drug substance (i.e., active ingredient) and drug product (i.e., oral tablets).

- Cassava Sciences expects to conclude a long-term, commercial drug supply agreement for simufilam with a contract manufacturing organization. The goal is to ensure the integrity of the drug supply chain on a worldwide basis, in compliance with FDA standards.

- Cassava Sciences expects to initiate a validation study with SavaDx, its investigational diagnostic for the detection of Alzheimer's disease.

- Cassava Sciences is in discussions with scientific and clinical advisors about potentially expanding therapeutic indications for simufilam outside of Alzheimer's disease, but still within neurodegenerative conditions.

Other Expected Milestones and Announcements for 2021

- ***Cassava Sciences expects to announce publication of Phase 2b results in a peer-reviewed technical journal.***

- Net cash use for full-year 2021 is expected to be in the range of $20 to $25 million, depending on enrollment rates in its clinical programs and other factors. On December 31, 2020, unaudited cash and cash equivalents were approximately $93 million.

34. On February 10, 2021, Cassava announced and on February 12, 2021 Cassava completed its $200 million Offering of more than four million shares of its common stock at $49 per share.

35. On February 22, 2021, Cassava issued a press release entitled "Cassava Sciences Announces Positive End-of-Phase 2 Meeting with FDA and Outlines Pivotal Phase 3 Program for Simufilam in Alzheimer's Disease." It stated, in relevant part:

- Two Upcoming Phase 3 Studies and a Previously Completed Phase 2 Program Support a New Drug Application Filing for Simufilam in Alzheimer's disease -

- Agreement Reached to Use ADAS-Cog as Co-Primary Efficacy Endpoint -

- Pivotal Phase 3 Program Remains On-track to be Initiated 2nd Half 2021 -

[. . . .] Cassava Sciences, Inc. (Nasdaq: SAVA), a biotechnology company developing product candidates for Alzheimer's disease, today announced the successful completion of an End-of-Phase 2 (EOP2) meeting with the U.S. Food and Drug Administration (FDA) for simufilam, its lead drug candidate for the treatment of Alzheimer's disease. ***Official EOP2 meeting minutes indicate FDA and Cassava Sciences agree on key elements of a pivotal Phase 3 clinical program in support of a New Drug Application (NDA) filing for simufilam in Alzheimer's disease.*** Agreements reached during the EOP2 meeting show a clear path forward for advancing simufilam into Phase 3 studies in the second half of 2021.

"For over 10 years we've been doing basic research and early drug development with simufilam," said Remi Barbier, President & CEO. "We are excited to finally advance simufilam into pivotal Phase 3 clinical studies in people with Alzheimer's disease. We believe the underlying science is solid, the drug appears safe and the clinical roadmap makes sense. We've crossed the Rubicon."

"We appreciate the valuable guidance and flexibility FDA has provided," added Jim Kupiec, MD, Cassava Sciences' Chief Clinical Development Officer. "We look forward to continuing a collaborative dialogue throughout the pivotal Phase 3 clinical development program."

Simufilam is a novel drug, discovered at Cassava Sciences, that targets both neuroinflammation and neurodegeneration. ***The EOP2 meeting discussion was supported by years of scientific and clinical data, including positive results from a previously completed Phase 2 clinical program with simufilam in Alzheimer's disease. In a double-blind, randomized, placebo-controlled Phase 2b study, simufilam demonstrated robust effects on primary and secondary outcome measures, with no safety issues. Recently, the Company announced that simufilam improved cognition in subjects with Alzheimer's disease in a 6-month interim analysis of an open-label study, with no safety issues.***

The EOP2 meeting took place mid-January. FDA attendees included Robert Temple, MD, Deputy Center Director for Clinical Science and Senior Advisor in the Office of New Drugs; Billy Dunn, MD, Director, Office of Neuroscience; Eric Bastings, MD, Director, Division of Neurology, and others.

Official meeting minutes confirm that Cassava Sciences and FDA are aligned on key elements of a Phase 3 clinical program for simufilam. FDA has agreed that the completed Phase 2 program, together with an upcoming and well-defined Phase 3 clinical program, are sufficient to show evidence of clinical efficacy for simufilam in Alzheimer's disease. There is also agreement that the use of separate clinical scales to assess cognition (ADAS-cog1) and function (ADCS-ADL2) are appropriate co-primary endpoints of efficacy. A clinical scale that combines cognition and function, such as iADRS3, is a secondary efficacy endpoint.

36. On March 9, 2021, Cassava announced that it had entered into a pharmaceutical supply agreement for a "large-scale, clinical-grade quantities of simufilam, a drug candidate for the treatment of Alzheimer's disease."

37. On March 23, 2021, Cassava issued a press release announcing its "Full-year 2020 Financial Results and Business Highlights." In addition to repeating much of the same business updates provided over the previous few weeks, the press release quoted Defendants Barbier and Schoen, stating, in relevant part:

> "In Q1 2021 we announced that our lead drug candidate, simufilam, improved cognition scores in 50 patients with Alzheimer's disease who completed at least 6 months of open-label treatment," said Remi Barbier, President & CEO. "In mid-2021, we look forward to announcing cognition scores in patients who'll have completed at least 12 months of open-label treatment with simufilam. To our knowledge, no drug has stabilized, much less improved, cognition scores over 12 months in patients with Alzheimer's disease. For this reason, I feel there is a sense of anticipation around the upcoming release of 12-month clinical data from our open-label study, as well as our plans to conduct a pivotal Phase 3 program with simufilam in the second half of 2021. With solid science, the right people in place, cash in the bank and a clinical roadmap that makes sense, I think Cassava Sciences is positioned to becoming a premier organization to serve patients with Alzheimer's disease."
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> "We have approximately $280 million in cash on our balance sheet, against expected cash use of approximately $20 to $25 million in 2021," said Eric Schoen, Chief Financial Officer. "We believe our cash levels support a pivotal Phase 3 clinical program of simufilam in Alzheimer's disease."

38. The same day, Cassava filed its annual report on Form 10-K for the period ended December 31, 2020 (the "2020 10-K"), affirming the previously reported financial results. The Company further stated:

> ***Since 2017, we have concentrated a substantial portion of our research and development efforts on the treatment and detection of Alzheimer's disease, an area of research that has seen significant failure rates. Further, our product candidates are based on new scientific approaches and novel technology, which makes it difficult to predict the time and cost of product candidate development and likelihood of success.***

Since 2017, we have concentrated a substantial portion of our research and development efforts on experimental methods for the treatment and detection of Alzheimer's disease. Prior efforts by biopharmaceutical companies to develop new treatments for Alzheimer's disease have seen very limited clinical success. No new treatments have been approved for Alzheimer's disease since 2003, and since that time, while many large clinical studies have been completed, no drug candidate has shown clear evidence of clinical efficacy in large, Phase 3 clinical studies. FDA-approved drugs for Alzheimer's disease only address symptoms, and there are no FDA-approved disease modifying therapeutics available for patients with Alzheimer's disease. Notwithstanding these substantial challenges to date, we seek to improve brain health by addressing the neurodegeneration and neuroinflammation components of Alzheimer's disease. Our lead drug candidate for Alzheimer's disease is based on a new approach of stabilizing – but not removing – a critical protein in the brain. We cannot be certain that our novel technologies will lead to an approvable or marketable product. In addition, because FDA has limited comparators to evaluate our lead drug candidate, we could experience a longer than expected regulatory review process and increased development costs.

39. The 2020 10-K further stated:

Our clinical studies may fail to demonstrate substantial evidence of the safety and efficacy of our product candidates, which would prevent, delay, or limit the scope of regulatory approval and commercialization.

* * *

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. Failure can occur at any time during the clinical study process. The results of preclinical studies of our product candidates may not be predictive of the results of early-stage or later-stage clinical studies, and results of early clinical studies of our product candidates may not be predictive of the results of later-stage clinical studies. The results of clinical studies in one set of patients or disease indications may not be predictive of those obtained in another. In some instances, there can be significant variability in safety or efficacy results between different clinical studies of the same product candidate due to numerous factors, including changes in study procedures set forth in protocols, differences in the size and type of the patient populations, changes in and adherence to the dosing regimen, and other clinical study protocols and the rate of dropout among clinical study participants. Open-label extension studies may also extend the timing and cost of a clinical study substantially. Product candidates in later stages of clinical studies may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical studies. Many companies in the biopharmaceutical industry have suffered significant setbacks in advanced clinical studies due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier studies. This is particularly true in neurodegenerative

diseases, where failure rates historically have been higher than in many other disease areas. Most product candidates that begin clinical studies are never approved by regulatory authorities for commercialization.

* * *

In addition, even if such clinical studies are successfully completed, we cannot guarantee that FDA or foreign regulatory authorities will interpret the results as we do, and more studies could be required before we submit our product candidates for approval. To the extent that the results of the studies are not satisfactory to FDA or foreign regulatory authorities for support of a marketing application, we may be required to expend significant resources, which may not be available to us, to conduct additional studies in support of potential approval of our product candidates. Even if regulatory approval is secured for any of our product candidates, the terms of such approval may limit the scope and use of our product candidates, which may also limit its commercial potential.

40. On April 21, 2021, Cassava issued a press release announcing its first quarter 2021 financial results, which stated, in relevant part:

- 9 Month Interim Analysis of Open-label Study to be Presented at a Major Scientific Conference in July 2021 as an Oral Presentation -

- Initiation of Pivotal Phase 3 Program Remains On-track for 2nd Half 2021 -

- Initiation of Cognition Maintenance Study On-track for June 2021 -

- Cash and cash equivalents were $282.2 million at March 31, 2021 -

[. . . .] Cassava Sciences, Inc. (Nasdaq: SAVA), a clinical-stage biotechnology company focused on Alzheimer's disease, today announced financial results for the first quarter ended March 31, 2021 and guidance regarding the release of new clinical data with simufilam. Simufilam is the Company's lead drug candidate to treat Alzheimer's disease.

"Alzheimer's is a progressive disease, so a patient's cognition is expected to worsen over time," said Remi Barbier, President & CEO. "***Patients' cognition scores actually improved following 6 months of open-label treatment with simufilam.*** Showing similar drug effects following 9 months of open-label treatment would be remarkable, yet consistent with simufilam's mechanism of action. Eventually, we'd like this drug candidate to benefit cognition for a year or longer."

In July 2021, Cassava Sciences plans to announce results of a pre-specified interim analysis that summarizes safety and cognition data on approximately the first 50 subjects to complete at least 9 months of open-label drug treatment. The Company

will present these data July 26 - 29th at the 2021 Alzheimer's Association International Conference (AAIC). AAIC's scientific committee has invited the Company's scientists to present the dataset as an oral presentation.

About the Open-label Study with Simufilam

In March 2020, Cassava Sciences initiated a long-term, open-label study to evaluate simufilam in patients with Alzheimer's disease. This study is funded by a research grant award from the National Institutes of Health (NIH). The open-label study is intended to monitor the long-term safety and tolerability of simufilam 100 mg twice-daily for 12 months or longer in patients with Alzheimer's disease. Another study objective is to measure changes in cognition on ADAS-Cog, a standard test of cognition in Alzheimer's disease. The study's clinical protocol has pre-specified cognition measurements at 6, 9 and 12 months.

The study's target enrollment is approximately 150 subjects with mild-to-moderate Alzheimer's disease (recently increased by 50 subjects). One-hundred subjects have enrolled in this study across multiple clinical sites in the U.S. and Canada.

On February 2, 2021, Cassava Sciences announced positive results of a first interim analysis that summarizes clinical data on the first 50 subjects to complete 6 months of open-label treatment. Patients' cognition scores improved from baseline following 6 months of simufilam treatment, with no safety issues. Six months of simufilam treatment improved cognition scores by 1.6 points on ADAS-Cog11, a 10% mean improvement from baseline to month 6.

In September 2021, Cassava Sciences plans to announce results of an interim analysis that summarizes safety and cognition data on approximately the first 50 subjects to complete at least 12 months of open-label drug treatment.

About the Cognition Maintenance Study (CMS)

In June 2021, Cassava Sciences plans to initiate a double-blind, randomized, placebo-controlled study in patients with Alzheimer's disease. Patients who have completed at least one year of open-label treatment with simufilam qualify to enroll in the Cognition Maintenance Study (CMS). Study subjects in the CMS will be randomized (1:1) to simufilam or placebo for six months. The CMS is designed to compare simufilam's effects on cognition in Alzheimer's patients who continue with drug treatment versus patients who discontinue drug treatment.

41. On June 21, 2021, Cassava issued a press release to "Provide[] Mid-Year Corporate Update, Clinical Development Progress and Announce[] Guidance on Clinical Data Release." That press release stated, in relevant part:

- **Open-label Study Completes Patient Enrollment**
- **Cognition Maintenance Study Initiated May 2020, now 30% Enrolled**
- **6-month Biomarker Data to be Presented at AAIC Conference in July**
- **9-month Safety & Cognition Data to be Presented at AAIC Conference**
- **Clinical Results with SavaDx to be Presented at AAIC Conference**
- **Phase 3 Program Initiation Remains On-track for 2nd Half 2021**

. . . [Cassava] today announced a mid-year update that highlights clinical development progress and provides guidance on upcoming data releases for simufilam and SavaDx. Simufilam is Cassava Sciences' lead drug candidate to treat Alzheimer's disease; SavaDx is an investigational diagnostic candidate to detect Alzheimer's with a simple blood test.

"Patients with Alzheimer's want clear and present evidence of drug efficacy," said Remi Barbier, President & CEO. "The recent regulatory approval of a new drug for Alzheimer's was a bit of a donnybrook over this very topic. ***Our clinical strategy with simufilam is to show real-world safety and efficacy by conducting both, randomized controlled trials, and an on-going open-label study.*** Ideally, biomarker and cognition data from our studies converge and result in health benefits for patients."

Clinical progress across Cassava Sciences' product portfolio is summarized below.

Update on Open-label Study with Simufilam

* * *

The open-label study has completed its target enrollment of 150 subjects. By physician and patient request, clinical sites may continue to enroll additional subjects up through the initiation of the Company's Phase 3 pivotal program of simufilam.

Guidance on Clinical Data Release

Cassava Sciences plans to announce results of an interim analysis on safety and cognition for the first 50 subjects to complete 9 months of open-label drug treatment. These cognition data will be presented at the 2021 Alzheimer's Association International Conference (AAIC) in Denver, CO, the week of July 26-30th. The scientific committee of AAIC has invited the Company's scientists to present these data as an oral presentation.

- Cassava Sciences will also present at AAIC biomarker data from the open-label study, including:

- Biomarkers of Alzheimer's disease: amyloid beta42, total tau, P-tau181.

- Biomarkers of neurodegeneration: neurogranin, neurofilament light chain (NfL).

- Biomarkers of neuroinflammation: YKL-40, sTREM2 and HMGB1.

Biomarker data were analyzed from cerebrospinal fluid (CSF) collected from twenty-five study subjects who underwent a small volume lumbar puncture at baseline and again after completing 6 months of open-label drug treatment.

* * *

Update on the Phase 3 Clinical Program

Cassava Sciences plans to initiate a Phase 3 program of simufilam in Alzheimer's disease in the second half of 2021. A clinical research organization (CRO) has been selected and will be publicly announced shortly. Large-scale, cGMP drug production capabilities are in-place to support the Phase 3 clinical program.

42. On July 26, 2021, Cassava issued a press release announcing "positive data with SavaDx from a randomized controlled Phase 2b study of Simufilam," stating, in relevant part:

- SavaDx Detected Significant Changes in Plasma Levels of Altered Filamin A in Patients with Alzheimer's Disease Before and After Simufilam Treatment

- Simufilam 100 mg and 50 mg Reduced Plasma Levels of Altered Filamin A in Alzheimer's Patients 48% (p=0.003) and 44% (p=0.02) Respectively

- Plasma Results with SavaDx Track Plasma Results with p-Tau181

- Plasma Data Provide Evidence of Target Engagement

Cassava Sciences, Inc. (Nasdaq: SAVA) today announced positive clinical data with SavaDx, an investigational diagnostic/biomarker to detect Alzheimer's disease with a simple blood test. SavaDx was used to measure plasma levels of altered filamin A before and after simufilam treatment in patients with Alzheimer's disease. In this Phase 2b randomized, controlled trial sponsored by the National Institutes of Health (NIH), simufilam significantly reduced plasma levels of altered filamin A in Alzheimer's patients treated for 28 days. Plasma levels of p-tau181 also dropped significantly in these same patients.

Simufilam 100 mg and 50 mg reduced plasma levels of altered filamin A by 48% (p=0.003) and 44% (p=0.02) respectively, versus placebo. Additionally, simufilam 100 mg and 50 mg reduced plasma levels of p-tau181 by 17% (p=0.01) and 15% (p=0.02) respectively, versus placebo. Plasma p-tau181 is a biomarker that is known to be elevated in Alzheimer's disease.

"We believe altered filamin A is a major culprit in Alzheimer's disease," said Remi Barbier, President & CEO. "Before simufilam treatment, SavaDx detected high plasma levels of altered filamin A in patients. After simufilam treatment, levels dropped significantly. We believe these data provide clear evidence that simufilam binds to and engages its intended target to produce treatment effects."

Treatment effects on CSF biomarkers for this Phase 2b study have been previously reported.

43. On July 29, 2021, Cassava issued a press release announcing "positive biomarker data with Simufilam in Alzheimer's Disease," stating, in relevant part:

- Simufilam Significantly Improved Biomarkers in Alzheimer's Patients Treated for 6 Months

- Robust Improvements Seen in All Measured Biomarkers of Disease, Neurodegeneration and Neuroinflammation ($p < 0.00001$)

- Biomarker Improvements Track with Cognitive Improvements

* * *

Cassava Sciences, Inc. (Nasdaq: SAVA) today announced positive biomarker data from an open-label study of simufilam, the Company's investigational drug for the treatment of Alzheimer's disease.

In a clinical study funded by the National Institutes of Health (NIH), simufilam significantly improved all measured biomarkers in patients with Alzheimer's disease following 6 months of open-label treatment. Biomarkers are objective biological data. There are no placebo effects.

Cerebrospinal fluid (CSF) biomarkers of disease pathology, t-tau and p-tau181, decreased 38% and 18%, respectively (both $p<0.00001$). CSF biomarkers of neurodegeneration, neurogranin and Nfl, decreased 72% and 55%, respectively (both $p<0.00001$). CSF biomarkers of neuroinflammation, sTREM2 and YKL-40, decreased 65% and 44% (both $p<0.00001$). CSF biomarker data were collected from 25 patients with mild-to-moderate Alzheimer's disease who completed 6 months of simufilam treatment in an on-going open-label study.

> "Six months of simufilam treatment robustly improved brain biomarkers," said Remi Barbier, President & CEO. "In this same study simufilam also improved cognition. These data suggest simufilam has potential to provide durable treatment effects for people living with Alzheimer's."

44. The above statements identified in ¶¶ 30-31, 33, 35, and 37-43 were materially false and/or misleading, and failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors that: (1) the quality and integrity of the scientific data supporting Cassava's claims for simufilam's efficacy had been overstated; (2) data underlying the foundational research for Cassava's product candidates had been manipulated; (3) experiments using post-mortem human brain tissue frozen for nearly 10 years was contrary to a basic understanding of neurobiology; (4) biomarker analysis for patients treated with simufilam had been manipulated to conclude that simufilam was effective; (5) as a result of the foregoing, there was a reasonable likelihood that Cassava would face regulatory scrutiny in connection with the development of simufilam; and (6) as a result of all the foregoing, Defendants' positive statements during the Class Period about the Company's business metrics and financial prospects and the likelihood of FDA approval were false and misleading and/or lacked a reasonable basis.

The Truth Begins to Emerge but Defendants Continue to Issue Materially Misleading Statements

45. On July 29, 2021, Cassava issued a press release entitled "Cassava Sciences Announces Positive Cognition Data With Simufilam in Alzheimer's Disease." Although the press release touted supposedly positive cognition data, analysts and industry observers noted that the data had not demonstrated that simufilam was more effective at improving cognition than Biogen's drug aduhelm.

46. On this news, Cassava's share price fell $65.77, or 48.61%, over two trading days, to close at $69.53 per share on July 30, 2021. Despite this decline in the Company's share price, Cassava securities continued to trade at artificially inflated prices throughout the remainder of the Class Period because of Defendants' continued misstatements and omissions regarding simufilam.

47. For example, in the same July 29, 2021 press release entitled "Cassava Sciences Announces Positive Cognition Data With Simufilam in Alzheimer's Disease," Cassava touted the data underlying simufilam's supposedly positive results in improving cognition, stating, in relevant part:

- Simufilam Significantly Improves Cognition in Patients with Alzheimer's in Interim Analysis of Open-label Study at 9 Months
- Cognition Improved 3.0 Points on ADAS-Cog at 9 Months ($p<0.001$)
- Cognitive Improvements Track with Biomarker Improvements
- No Behavior Disorders in Over 50% of Patients
- No Safety Issues
- Improvements in Cognition, Biomarkers and Behavior Suggest Highly Encouraging Treatment Effects

* * *

> Cassava Sciences, Inc. (Nasdaq: SAVA) announced positive clinical data today from an interim analysis of an open-label study with simufilam, the Company's investigational drug for the treatment of Alzheimer's disease.
>
> In a clinical study funded by the National Institutes of Health (NIH), simufilam significantly improved cognition in Alzheimer's patients, with no safety issues. Simufilam improved cognition scores 3.0 points on ADAS-Cog11, an 18% mean improvement, baseline to month 9 ($p<0.001$). This interim analysis summarizes clinical data from the first 50 patients with mild-to-moderate Alzheimer's disease who completed 9 months of open-label simufilam treatment.
>
> Cassava Sciences believes today's data is the first report of significant cognitive improvements at 9 months that also track with robust improvements in biomarkers in patients with Alzheimer's.

"We are very pleased with the overall consistency of data," said Remi Barbier, President & CEO. "Simufilam improved cognition, biomarkers and behavior, a triple-win for study participants. These clinical data combined with a clean safety profile and easy oral administration suggest highly encouraging and durable treatment effects for people living with Alzheimer's disease."

Alzheimer's is a progressive disease. Cognition will always decline over time. In patients with mild-to-moderate Alzheimer's disease, cognition scores decline over 4 points on ADAS-Cog over 9 months with over 90% certainty, as reported by the science literature[].

Simufilam improved ADAS-Cog scores in 66% of patients at 9 months. An additional 22% of patients declined less than reported in the science literature at 9 months. Cognition outcomes suggest simufilam's treatment effects were broad-based.

Alzheimer's is often accompanied by behaviors disorders, such as anxiety, agitation or delusions. These may become more frequent as disease progresses. Simufilam reduced dementia-related behavior at 9 months on the Neuropsychiatric Inventory (NPI), a clinical tool widely used to measure changes in dementia-related behavior.

- At baseline, 34% of study subjects had no neuropsychiatric symptoms.
- At month 6, 38% of study subjects had no neuropsychiatric symptoms.
- At month 9, over 50% of study subjects had no neuropsychiatric symptoms.

The safety profile of simufilam in the interim analysis is consistent with prior human studies. There were no drug-related serious adverse events. Adverse events were mild and transient.

"Today's data with simufilam suggests disease modification," added Nadav Friedmann, PhD, MD, Chief Medical Officer. "It appears the drug's unique mechanism of action has potential to provide transformative treatment benefits following 9 months of dosing."

In February 2021, Cassava Sciences reported that simufilam improved cognition scores by 1.6 points on ADAS-Cog11, a 10% improvement, following six months of open-label treatment.

48. On August 24, 2021, Cassava issued a press release announcing that it had entered into an "Agreement with FDA on Special Protocol Assessments (SPA) for its Phase 3 Studies of Simufilam for the Treatment of Alzheimer's Disease." That press release stated, in relevant part:

> These SPA agreements document that FDA has reviewed and agreed upon the key design features of Cassava Sciences' Phase 3 study protocols of simufilam for the treatment of patients with Alzheimer's disease.
>
> "I believe these SPAs mark a meaningful and encouraging milestone for Cassava Sciences," said Remi Barbier, President & CEO. "The SPAs underscore our alignment with FDA on key scientific, clinical and regulatory requirements of our Phase 3 program of simufilam in Alzheimer's disease."
>
> Cassava Sciences also reaffirmed prior guidance to advance simufilam into a Phase 3 pivotal program in Alzheimer's disease in Fall 2021.

49. The above statements identified in ¶¶ 47-48 were materially false and/or misleading, and failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors that: (1) the quality and integrity of the scientific data supporting Cassava's claims for simufilam's efficacy had been overstated; (2) data underlying the foundational research for Cassava's product candidates had been manipulated; (3) experiments using post-mortem human brain tissue frozen for nearly 10 years was contrary to a basic understanding of neurobiology; (4) biomarker analysis for patients treated with simufilam had been manipulated to conclude that simufilam was effective; (5) Quanterix Corp. ("Quanterix"), an independent company, had not interpreted the test results or prepared the data charts for the biomarker analysis for patients treated with simufilam; (6) as a result of the foregoing, there was a reasonable likelihood that Cassava would face regulatory scrutiny in connection with the development of simufilam; and (7) as a result of all the foregoing, Defendants' positive statements during the Class Period about the Company's business metrics and financial prospects and the likelihood of FDA approval were false and misleading and/or lacked a reasonable basis.

50. On August 24, 2021, after the market closed, reports emerged about a citizen petition submitted to the FDA concerning the accuracy and integrity of clinical data for simufilam.

The petition requested that the FDA halt Cassava's clinical trials pending a thorough audit of the publications and data relied upon by the Company. Among other things, the petition stated that the "[d]etailed analysis of the western blots [relied on by Cassava to support the connection between simufilam and Alzheimer's] shows a series of anomalies that are suggestive of systematic data manipulation and misrepresentation." It also stated that the methodology for studies "about Simufilam's effects in experiments conducted on postmortem human brain tissue . . . defies logic, and the data presented again have hallmarks of manipulation." The petition further stated that, after initial analyses of Phase 2b trials found that Simufilam was ineffective in improving the primary biomarkers endpoint, "Cassava had these samples analyzed again and this time reported that Simufilam rapidly and robustly improved a wide array of biomarkers" and the reanalysis "shows signs of data anomalies or manipulation." Specifically, the statement of grounds for the petition stated, in relevant part:

> Petitioner has enclosed with this Petition (and incorporates herein) a detailed technical report presenting multiple reasons to question the quality and integrity of the research supporting Cassava's claims about Simufilam's use for Alzheimer's Disease. In sum, that report explains:
>
> (1) All of the foundational science supporting Cassava's claims about Simufilam's use for Alzheimer's Disease comes from a series of papers with two common co-authors (Dr. Hoau-Yan-Wang at City University of New York and Dr. Lindsay Burns of Cassava). The studies of Drs. Wang and Burns were used by Cassava to obtain NIH grants and to open an Investigational New Drug (IND) application to study Simufilam. They form the foundation for the current clinical trials of Simufilam.
>
> (2) No other lab has confirmed Cassava's research connecting Filamin A to Alzheimer's Disease, nor has any other lab confirmed that Simufilam binds or modifies Filamin A or has effects in Alzheimer's Disease models.
>
> (3) Close review of the data and analyses in the foundational research papers and Cassava's recent publications of clinical trial analyses presents primary areas of concern:

a. The underlying papers of Drs. Wang and Burns involve extensive use of Western blot analyses to support their claims connecting Simufilam to Alzheimer's. Detailed analysis of the western blots in the published journal articles shows a series of anomalies that are suggestive of systematic data manipulation and misrepresentation.

b. Some of the foundational studies published by Drs. Wang and Burns make claims about Simufilam's effects in experiments conducted on postmortem human brain tissue. The methodology allegedly used in those experiments defies logic, and the data presented again have the hallmarks of manipulation.

c. Cassava's presentation of clinical biomarker data from the Phase 2b trials raises questions about the validity of the data. The CSF samples in this study were first analyzed by an outside lab, which found that Simufilam was ineffective in improving the primary biomarkers end point and high variability in other biomarkers. But Cassava had these samples analyzed again and this time reported that Simufilam rapidly and robustly improved a wide array of biomarkers. Cassava has not fully published the data from this reanalysis, but a presentation poster that it published on July 26, 2021, which appears to describe aspects of that work, shows signs of data anomalies or manipulation.

(4) Six further aspects of the research by Drs. Wang and Burns are incompatible with scientific norms, and these claims raise further suspicions.

d. Remarkably High Affinity Binding Between PTI-125 and Filamin A.

e. Remarkably High Affinity Binding Between Naloxone and Filamin A

f. Isoelectric Focusing Experiments in Multiple Papers Indicate 100% of Filamin in Altered Conformation in Alzheimer's Disease and largely Restored to Correct Conformation by PTI125.

g. Novel Blood Diagnostic SavaDx Represents Plasma Filamin A Level

h. PTI-125/Simufilam Improves Memory in a Mouse Model of Alzheimer's Disease.

i. PTI-125/Simufilam Blocks the Interaction Between B-amyloid and x7 – Nicotinic Acetylcholine Receptors.

51. The statement of concern (incorporated into the petition by reference) further stated:

In this document, three primary concerns are raised:

- The validity of clinical biomarker data: Biomarker analysis from patients treated with simufilam in Cassava's double-blind study forms a primary basis of Cassava's claim that simufilam engages its target in the central nervous systems, but there are concerns about the integrity of this data. The CSF samples in this study were analyzed by an outside lab, which found that simufilam was ineffective in improving the primary biomarker end point and showed high variability in other biomarkers. However, Cassava Science had these samples bioanalyzed again and the data were finalized in an academic lab, which apparently refers to Dr. Wang. This re-analysis showed that simufilam rapidly and robustly improved a wide array of CSF biomarkers. Whereas Cassava has not fully published this reanalysis, Cassava's 26 July 2021 poster presumably describing aspects of that work shows signs of data manipulation.

- The integrity of western blot analyses: Western blotting was extensively used by Drs. Wang and Burns over the past 15 years to support their foundational scientific claims and underscores their SavaDx clinical plasma biomarker. Detailed analysis of the western blots in the published journal articles from Drs. Wang and Burns shows a series of anomalies. The extent of these anomalies forms a 15-year pattern that strongly suggests systematic data manipulation and misrepresentation.

- The integrity of analyses involving human brain tissue: Simufilam is reported to bind to its target and modify a range of downstream molecules in experiments conducted on post-mortem human brain tissue from subjects with Alzheimer's disease and neurological controls. The same human brain specimens are used across the studies from 2008-2017, so the results are premised on human neurons remaining viable up to 13 hours after death, then being successfully reanimated after nearly 10 years in frozen archival without any advanced cryopreservation techniques. The complex, multi-step cellular processes the authors claim to observe in tissue that has been dead for a decade are contrary to a basic understanding of neurobiology. As with the western blot data, there are anomalies in the presentation of the data which again strongly suggests manipulation.

52. After summarizing its findings, the Citizen Petition went on to conclude that "the extensive evidence set forth in the enclosed report, which presents grave concerns about the quality and integrity of the scientific data supporting Cassava's claims for Simufilam's efficacy, provides compelling grounds for pausing the ongoing clinical trials until the FDA can conduct and complete a rigorous audit of Cassava's research."

53. On August 25, 2021, before the market opened, Cassava issued a response to the petition, claiming that the allegations regarding scientific integrity are false and misleading. Specifically, it stated:

> **Fiction:** Biomarker data is generated by Cassava Sciences or its science collaborators and therefore are falsified.
>
> ***Fact: Cassava Sciences' plasma p-tau data from Alzheimer's patients was generated by Quanterix Corp., an independent company, and presented at the recent Alzheimer's Association International Conference[].***
>
> ***Fiction: Plasma p-tau for one individual Alzheimer's patient increased by 235%, which was not shown in the scatterplot.***
>
> **Fact:** This patient's plasma p-tau increased by 38%, not 235%, as shown in a scatterplot.[]
>
> **Fiction:** Tissue staining showing Abeta42 inside neurons shows treatment effects.
>
> **Fact:** Yes, Abeta42 is indeed inside neurons prior to plaque formation.
>
> **Fiction:** The author's Citizen Petition to FDA dated August 18, 2021, is evidence of wrongdoing.
>
> **Fact:** Five days after the Citizen's Petition, Cassava Sciences announced it had reached an agreement with FDA on Special Protocol Assessments (SPA) for its Phase 3 studies of simufilam for the treatment of Alzheimer's disease. The SPAs underscore alignment with FDA on key scientific, clinical and regulatory requirements of the Company's Phase 3 program of simufilam in Alzheimer's disease.[] Furthermore, a Citizen's Petition allows any party to raise safety/efficacy concerns with drugs the FDA is considering for approval, which is not the case for Cassava Sciences' simufilam.[]
>
> **Fiction:** Extensive use of Western blot analysis is foundational to Cassava Sciences' research and therefore suspicious.
>
> **Fact:** Western blot analysis is foundational to the biotechnology industry[]. Western blotting is a standard lab technique used world-wide to detect a protein of interest.
>
> **Fiction:** Cassava Sciences' Western blots data appear overexposed and highly processed, evidence of image manipulation.

Fact: High quality bands are supposed to look sharp6[] Smudged bands can be evidence of inexperience, depending on levels of protein in the band.

Fiction: Western blots data are identical, more evidence of image manipulation.

Fact: The Western blots bands shown in the allegation are control bands. Control bands are supposed to be highly similar (since they show equal amounts of protein between lanes). Bands show clear differences when expanded. In addition, image manipulation of control bands makes no sense since these would not change the end data.

Fiction: "Halo" effects in certain bands indicate fraud.

Fact: A "Halo" effects in certain bands is a direct result of very dense dark loading control bands.[]

Fiction: Unusual looking bands on Western blots were pieced together from multiple sources.

Fact: Proteins can and do stick to the side of a lane and migrate that way, resulting in 'candy-wrapper' appearance or other fictional images.

Fiction: Femtomolar binding affinity is unusual and suspicious.

Fact: Femtomolar binding affinity is a fundamental property of simufilam and may account for its relative potency and safety.

Fiction: Post-mortem brain tissue that is dead for a decade is unreliable.

Fact: Because of the inaccessibility of the human brain and its unavailability for biopsy, translational medicine can rely on post-mortem tissue[]. In our case, human brain tissue was collected within 6 hours of death, flash-frozen and stored at -80 Centigrade. This is a standard procedure for pathologists. Such tissue processing is also used in cancer and other fields. Cassava Sciences is not aware of an industry-wide 'expiration date' on human post-mortem brain tissue that is properly collected, processed and stored.

Fiction: Isoelectric focusing gels should not have crisp bands, which is evidence of fraud.

Fact: Quality isoelectric focusing gels often do have crisp bands[].

Fiction: Changes in the Y-maze test for transgenic mice could be interpreted as a decline in cognition.

> **Fact:** A panel of independent, peer-reviewers believe these changes represent an improvement, along with significant improvements in two other behavior tests.
>
> **Fiction:** High-affinity binding of naloxone for filamin A is suspicious.
>
> **Fact:** Naloxone binds the same site on filamin A. Of course, it will have high-affinity binding.
>
> **Fiction:** Isoelectric focusing experiments indicate 100% of filamin A is in altered conformation in Alzheimer's disease and is largely restored to correct conformation by simufilam.
>
> **Fact:** Cassava Sciences agrees. This nicely describes the mechanism of action for simufilam.

[Footnotes omitted.]

54. On this news, the Company's share price fell $36.97, or 31.38%, to close at $80.86 per share on August 25, 2021, on unusually heavy trading volume. Despite this decline in the Company's share price, Cassava securities continued to trade at artificially inflated prices throughout the remainder of the Class Period because of Defendants' continued misstatements and omissions regarding simufilam.

55. The above statements identified in ¶ 53 were materially false and/or misleading, and failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors that: (1) Quanterix, an independent company, had not interpreted the test results or prepared the data charts for the biomarker analysis for patients treated with simufilam; (2) as a result of the foregoing, there was a reasonable likelihood that Cassava would face regulatory scrutiny in connection with the development of simufilam; and (3) as a result of all the foregoing, Defendants' positive statements during the Class Period about the Company's business metrics and financial prospects and the likelihood of FDA approval were false and misleading and/or lacked a reasonable basis.

The Truth Continues to Emerge

56. On August 27, 2021, before the market opened, Quanterix issued a statement denying Cassava's claims that Quanterix had interpreted the Company's clinical data. Specifically, it stated:

> Cassava previously engaged Quanterix' Accelerator laboratory to perform sample testing based on blinded samples provided by Cassava. ***Quanterix or its employees did not interpret the test results or prepare the data charts presented by Cassava at the Alzheimer's Association International Conference (AAIC) in July 2021 or otherwise.***
>
> Quanterix is widely recognized for its commitment to business integrity and to upholding the highest standards of quality. Quanterix' Simoa technology provides exquisite sensitivity for detecting and measuring biomarkers across a wide range of disease states, including neurology, oncology, and infectious disease. The Simoa technology has been trusted by 24 of the top 25 top pharmaceutical companies, and Quanterix customers have described the use of Simoa technology in over 1,300 research papers and presentations worldwide.
>
> Quanterix harnesses the power of biomarkers with the latest detection solutions to enable a precision health vision of proactive, preventative healthcare and believes that, in doing so, can change the course of how diseases like Alzheimer's are currently studied and treated.

57. The same day, Cassava responded to Quanterix's statement, stating that "Quanterix'[s] sole responsibility with regard to this clinical study was to perform sample testing, specifically, to measure levels of p-tau in plasma samples collected from study subjects." The Company's press release stated, in relevant part:

> The Phase 2b clinical study was conducted by Cassava Sciences. Quanterix' sole responsibility with regard to this clinical study was to perform sample testing, specifically, to measure levels of p-tau in plasma samples collected from study subjects.
>
> "To ensure data integrity, it is standard industry practice to keep separate the people who generate the data from the people who analyze the data," said Remi Barbier, President & CEO. "That certainly was the case here. Anything different is a distortion of the facts."

> Quanterix' sample testing was conducted entirely by its employees. Quanterix' employees were blind to treatment group, i.e., they did not know which samples were from placebo, or simufilam-treated patients. Quanterix conducted sample testing, then sent raw data to Cassava Sciences for analysis of treatment effects. Eventually, Cassava Sciences presented these data in a poster presentation at the Alzheimer's Association International Conference (AAIC) in July 2021. In keeping with scientific authorship guidelines, prior to submitting the abstract to AAIC, Cassava Sciences received permission from Quanterix to include its lab personnel in the author list.

58. On this news, the Company's share price fell $12.51, or 17.66%, to close at $58.34 per share on August 27, 2021, on unusually heavy trading volume.

PLAINTIFF'S CLASS ACTION ALLEGATIONS

59. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a class, consisting of all persons and entities that purchased or otherwise acquired Cassava securities during the Class Period, and who were damaged thereby (the "Class"). Excluded from the Class are Defendants, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors, or assigns, and any entity in which Defendants have or had a controlling interest.

60. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Cassava's shares actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are at least hundreds or thousands of members in the proposed Class. Millions of Cassava shares were traded publicly during the Class Period on the NASDAQ. Record owners and other members of the Class may be identified from records maintained by Cassava or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

61. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

62. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation.

63. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

(a) whether the federal securities laws were violated by Defendants' acts as alleged herein;

(b) whether statements made by Defendants to the investing public during the Class Period omitted and/or misrepresented material facts about the business, operations, and prospects of Cassava; and

(c) to what extent the members of the Class have sustained damages and the proper measure of damages.

64. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

UNDISCLOSED ADVERSE FACTS

65. The market for Cassava's securities was open, well-developed and efficient at all relevant times. As a result of these materially false and/or misleading statements, and/or failures

to disclose, Cassava's securities traded at artificially inflated prices during the Class Period. Plaintiff and other members of the Class purchased or otherwise acquired Cassava's securities relying upon the integrity of the market price of the Company's securities and market information relating to Cassava, and have been damaged thereby.

66. During the Class Period, Defendants materially misled the investing public, thereby inflating the price of Cassava's securities, by publicly issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make Defendants' statements, as set forth herein, not false and/or misleading. The statements and omissions were materially false and/or misleading because they failed to disclose material adverse information and/or misrepresented the truth about Cassava's business, operations, and prospects as alleged herein.

67. At all relevant times, the material misrepresentations and omissions particularized in this Complaint directly or proximately caused or were a substantial contributing cause of the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Cassava's financial well-being and prospects. These material misstatements and/or omissions had the cause and effect of creating in the market an unrealistically positive assessment of the Company and its financial well-being and prospects, thus causing the Company's securities to be overvalued and artificially inflated at all relevant times. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at artificially inflated prices, thus causing the damages complained of herein when the truth was revealed.

LOSS CAUSATION

68. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class.

69. During the Class Period, Plaintiff and the Class purchased Cassava's securities at artificially inflated prices and were damaged thereby. The price of the Company's securities significantly declined when the misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, were revealed, causing investors' losses.

SCIENTER ALLEGATIONS

70. As alleged herein, Defendants acted with scienter since Defendants knew that the public documents and statements issued or disseminated in the name of the Company were materially false and/or misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. As set forth elsewhere herein in detail, the Individual Defendants, by virtue of their receipt of information reflecting the true facts regarding Cassava, their control over, and/or receipt and/or modification of Cassava's allegedly materially misleading misstatements and/or their associations with the Company which made them privy to confidential proprietary information concerning Cassava, participated in the fraudulent scheme alleged herein.

APPLICABILITY OF PRESUMPTION OF RELIANCE (FRAUD-ON-THE-MARKET DOCTRINE)

71. The market for Cassava's securities was open, well-developed and efficient at all relevant times. As a result of the materially false and/or misleading statements and/or failures to disclose, Cassava's securities traded at artificially inflated prices during the Class Period. On July

28, 2021, the Company's share price closed at a Class Period high of $135.30 per share. Plaintiff and other members of the Class purchased or otherwise acquired the Company's securities relying upon the integrity of the market price of Cassava's securities and market information relating to Cassava, and have been damaged thereby.

72. During the Class Period, the artificial inflation of Cassava's shares was caused by the material misrepresentations and/or omissions particularized in this Complaint causing the damages sustained by Plaintiff and other members of the Class. As described herein, during the Class Period, Defendants made or caused to be made a series of materially false and/or misleading statements about Cassava's business, prospects, and operations. These material misstatements and/or omissions created an unrealistically positive assessment of Cassava and its business, operations, and prospects, thus causing the price of the Company's securities to be artificially inflated at all relevant times, and when disclosed, negatively affected the value of the Company's shares. Defendants' materially false and/or misleading statements during the Class Period resulted in Plaintiff and other members of the Class purchasing the Company's securities at such artificially inflated prices, and each of them has been damaged as a result.

73. At all relevant times, the market for Cassava's securities was an efficient market for the following reasons, among others:

(a) Cassava shares met the requirements for listing, and were listed and actively traded on the NASDAQ, a highly efficient and automated market;

(b) As a regulated issuer, Cassava filed periodic public reports with the SEC and/or the NASDAQ;

(c) Cassava regularly communicated with public investors via established market communication mechanisms, including through regular dissemination of press releases on

the national circuits of major newswire services and through other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and/or

(d) Cassava was followed by securities analysts employed by brokerage firms who wrote reports about the Company, and these reports were distributed to the sales force and certain customers of their respective brokerage firms. Each of these reports was publicly available and entered the public marketplace.

74. As a result of the foregoing, the market for Cassava's securities promptly digested current information regarding Cassava from all publicly available sources and reflected such information in Cassava's share price. Under these circumstances, all purchasers of Cassava's securities during the Class Period suffered similar injury through their purchase of Cassava's securities at artificially inflated prices and a presumption of reliance applies.

75. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128 (1972), because the Class's claims are, in large part, grounded on Defendants' material misstatements and/or omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects—information that Defendants were obligated to disclose—positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

NO SAFE HARBOR

76. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. In addition, to the extent certain of the statements alleged to be false may be characterized as forward looking, they were not identified as "forward-looking statements" when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements was made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, and/or the forward-looking statement was authorized or approved by an executive officer of Cassava who knew that the statement was false when made.

FIRST CLAIM

Violation of Section 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder Against All Defendants

77. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

78. During the Class Period, Defendants carried out a plan, scheme and course of conduct which was intended to and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; and (ii) cause Plaintiff and other members of the Class to purchase Cassava's securities at artificially inflated prices. In

furtherance of this unlawful scheme, plan and course of conduct, Defendants, and each defendant, took the actions set forth herein.

79. Defendants (i) employed devices, schemes, and artifices to defraud; (ii) made untrue statements of material fact and/or omitted to state material facts necessary to make the statements not misleading; and (iii) engaged in acts, practices, and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities in an effort to maintain artificially high market prices for Cassava's securities in violation of Section 10(b) of the Exchange Act and Rule 10b-5. All Defendants are sued either as primary participants in the wrongful and illegal conduct charged herein or as controlling persons as alleged below.

80. Defendants, individually and in concert, directly and indirectly, by the use, means or instrumentalities of interstate commerce and/or of the mails, engaged and participated in a continuous course of conduct to conceal adverse material information about Cassava's financial well-being and prospects, as specified herein.

81. Defendants employed devices, schemes and artifices to defraud, while in possession of material adverse non-public information and engaged in acts, practices, and a course of conduct as alleged herein in an effort to assure investors of Cassava's value and performance and continued substantial growth, which included the making of, or the participation in the making of, untrue statements of material facts and/or omitting to state material facts necessary in order to make the statements made about Cassava and its business operations and future prospects in light of the circumstances under which they were made, not misleading, as set forth more particularly herein, and engaged in transactions, practices and a course of business which operated as a fraud and deceit upon the purchasers of the Company's securities during the Class Period.

82. Each of the Individual Defendants' primary liability and controlling person liability arises from the following facts: (i) the Individual Defendants were high-level executives and/or directors at the Company during the Class Period and members of the Company's management team or had control thereof; (ii) each of these defendants, by virtue of their responsibilities and activities as a senior officer and/or director of the Company, was privy to and participated in the creation, development and reporting of the Company's internal budgets, plans, projections and/or reports; (iii) each of these defendants enjoyed significant personal contact and familiarity with the other defendants and was advised of, and had access to, other members of the Company's management team, internal reports and other data and information about the Company's finances, operations, and sales at all relevant times; and (iv) each of these defendants was aware of the Company's dissemination of information to the investing public which they knew and/or recklessly disregarded was materially false and misleading.

83. Defendants had actual knowledge of the misrepresentations and/or omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose such facts, even though such facts were available to them. Such defendants' material misrepresentations and/or omissions were done knowingly or recklessly and for the purpose and effect of concealing Cassava's financial well-being and prospects from the investing public and supporting the artificially inflated price of its securities. As demonstrated by Defendants' overstatements and/or misstatements of the Company's business, operations, financial well-being, and prospects throughout the Class Period, Defendants, if they did not have actual knowledge of the misrepresentations and/or omissions alleged, were reckless in failing to obtain such knowledge by deliberately refraining from taking those steps necessary to discover whether those statements were false or misleading.

84. As a result of the dissemination of the materially false and/or misleading information and/or failure to disclose material facts, as set forth above, the market price of Cassava's securities was artificially inflated during the Class Period. In ignorance of the fact that market prices of the Company's securities were artificially inflated, and relying directly or indirectly on the false and misleading statements made by Defendants, or upon the integrity of the market in which the securities trade, and/or in the absence of material adverse information that was known to or recklessly disregarded by Defendants, but not disclosed in public statements by Defendants during the Class Period, Plaintiff and the other members of the Class acquired Cassava's securities during the Class Period at artificially high prices and were damaged thereby.

85. At the time of said misrepresentations and/or omissions, Plaintiff and other members of the Class were ignorant of their falsity, and believed them to be true. Had Plaintiff and the other members of the Class and the marketplace known the truth regarding the problems that Cassava was experiencing, which were not disclosed by Defendants, Plaintiff and other members of the Class would not have purchased or otherwise acquired their Cassava securities, or, if they had acquired such securities during the Class Period, they would not have done so at the artificially inflated prices which they paid.

86. By virtue of the foregoing, Defendants violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

87. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their respective purchases and sales of the Company's securities during the Class Period.

SECOND CLAIM

Violation of Section 20(a) of the Exchange Act
Against the Individual Defendants

88. Plaintiff repeats and re-alleges each and every allegation contained above as if fully set forth herein.

89. The Individual Defendants acted as controlling persons of Cassava within the meaning of Section 20(a) of the Exchange Act as alleged herein. By virtue of their high-level positions and their ownership and contractual rights, participation in, and/or awareness of the Company's operations and intimate knowledge of the false financial statements filed by the Company with the SEC and disseminated to the investing public, the Individual Defendants had the power to influence and control and did influence and control, directly or indirectly, the decision-making of the Company, including the content and dissemination of the various statements which Plaintiff contends are false and misleading. The Individual Defendants were provided with or had unlimited access to copies of the Company's reports, press releases, public filings, and other statements alleged by Plaintiff to be misleading prior to and/or shortly after these statements were issued and had the ability to prevent the issuance of the statements or cause the statements to be corrected.

90. In particular, the Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, had the power to control or influence the particular transactions giving rise to the securities violations as alleged herein, and exercised the same.

91. As set forth above, Defendants each violated Section 10(b) of the Exchange Act and Rule 10b-5 by their acts and omissions as alleged in this Complaint. By virtue of their position as controlling persons, the Individual Defendants are liable pursuant to Section 20(a) of the

Exchange Act. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and other members of the Class suffered damages in connection with their purchases of the Company's securities during the Class Period.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

A. Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

B. Awarding compensatory damages in favor of Plaintiff and the other Class members against all defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

D. Such other and further relief as the Court may deem just and proper.

JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Dated: September 24, 2021

Respectfully submitted,

/s/ Willie C. Briscoe

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